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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,749	10/29/2003	William DeToro	3934	5373

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EXAMINER

WIEKER, AMANDA FLYNN

ART UNIT PAPER NUMBER

3743

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,749

Applicant(s)

DETORO ET AL.

Examiner

Amanda F. Wieker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 9 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/29/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: H and L (page 5).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities.

3. The specification recites that the leg engagement plates are being contoured to conform to the "medial leg portion". This language appears improper. It appears that this language should be replaced with language requiring the plates to conform to the posterior leg portion. Conventional terminology dictates that the term "medial" be used to describe the middle-facing portion of the body; the term "lateral" is used to describe the outward or side-facing portion of the body; the term "anterior" is used to describe the forward-facing portion of the body; and the term "posterior" is used to describe the backward-facing portion of the body.

In this case, the leg engagement plates are positioned on the back of the user's leg, i.e., against the posterior face of the leg. For the leg engagement plates to be located on the "medial"

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face of the leg as claimed, they would need to be placed along the inside of the user's leg, between the knee-cap and the back of the knee where hinge (20) is located. This is not disclosed or shown to be the case. As such, it appears that the specification should be amended to disclose the leg engagement plates' position to be relative to the posterior portion of the body.

Appropriate correction is required.

Claim Objections

4. Claims 9 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

5. Claims 1, 2, 4, 7-8 and 11 are objected to because of the following informalities:

Claim 1 recites that the upper and lower engagement plates are fitted "against the medial face of the leg above and below the knee". While this language is also provided in the specification, it appears improper. It appears that this language should be replaced with -- against the ~~medial~~ posterior face of the leg above and below the knee--.. Conventional terminology dictates that the term "medial" be used to describe the middle-facing portion of the body; the term "lateral" is used to describe the outward or side-facing portion of the body; the term "anterior" is used to describe the forward-facing portion of the body; and the term "posterior" is used to describe the backward-facing portion of the body.

In this case, the leg engagement plates are positioned on the back of the user's leg, i.e., against the posterior face of the leg. For the leg engagement plates to be located on the "medial" face of the leg as claimed, they would need to be placed along the inside of the user's leg, between the knee-cap and the back of the knee where hinge (20) is located. This is not disclosed

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or shown to be the case. As such, it appears the claim 1 should be amended to disclose the leg engagement plates' position to be relative to the posterior portion of the body.

6. In claim 2, --a-- should be inserted between "secured to" and "non-leg" in line 2.

7. In claim 4, at line 5, it appears that "apertured" should be replaced with --apertures--.

8. Claim 7 is somewhat confusing, because the phrase "positioning retaining straps," in line 3, reads as a method step (i.e., an instruction to "position the retaining straps"). However, it can be discerned from the specification that this limitation is not intended to be read as a method step. It is suggested the claim be amended as follows, to clearly recite apparatus, not method, limitations: --said knee stabilization means comprises a knee support pad overlying the wearer's knee, and positioning and retaining straps extending from said knee support pad.-- It is noted that the specification describes these straps as "positioning and retaining straps".

9. In claim 8 at line 1, it appears that "said knee" should be replaced with --said knee support pad--, as the "knee" does not have "interengagement means" as claimed.

10. In claim 11, it appears that the description of the reinforcement band being "secured inwardly from the perimeter edge surface" is improper. Per the Figures, see Figure 2 specifically, the reinforcement band (43) is secured along the outer perimeter of the support pad, and therefore does not extend "inwardly". Rather, the reinforcement band extends outwardly from the perimeter of the pad.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

A claim reciting a portion of, or an attachment to, the human body contains non-statutory subject matter. 1077 OG 24 (April 21, 1987). "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101". Accordingly, where a claim is directed to an apparatus "attached to" the human body or any part thereof, such a claim will be rejected under 35 U.S.C. 101, because the claim positively recites a part of the human body and therefore is directed to non-statutory subject matter.

Claim 1 recites an apparatus that is attached to a part of the human body. For example, in claim 1 Applicant recites "rigid upper and lower leg engagement plates *fitted against the medial face of the leg*". Applicant also recites in claim 1: "knee stabilization means *overlying said knee*". A claim reciting a portion of, or an attachment to, the human body contains non-statutory subject matter. Similarly, in claim 7, Applicant recites, "comprises a knee support pad *overlying the wearer's knee*".

Applicant can overcome this rejection by amending claim 1 to recite, --rigid upper and lower leg engagement plates adapted to be fitted against the medial face of the leg--, and --knee stabilization means adapted to overlie ~~overlying~~ said knee--. The rejection of claim 7 can be overcome by amending claim 7 to recite --comprises a knee support pad adapted to overlie ~~overlying~~ the wearer's knee--.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-2, 6-8 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,733,321 to Brink.

Brink discloses an adjustable therapeutic knee immobilization brace for controlling the degree of motion to a person's knee comprising;

a flexible sheet of cushion material (4) adapted to wrap around a wearer's leg extending above, below and encompassing the wearer's knee (see Figure 1),

rigid upper (10) and lower (12) leg engagement plates fitted against at least part of the medial (plate engages inner, medial leg) and posterior (back edge of plate engages posterior leg) faces of the leg above and below the knee (see Figures 1-2),

an adjustable locking hinge assembly (18/20) extending between and interconnecting said upper and lower leg engagement plates,

knee stabilization means (34) overlying said knee, and

means for adjustably securing (24) said knee immobilization brace to the wearer's leg.

Regarding claim 2, Brink discloses that the rigid upper and lower leg engagement plates are selectively secured to a non-leg engagement surface of said sheet of cushion material (see column 4, lines 19-22).

Regarding claim 5, the means for adjustably securing said knee immobilization brace to the wearer's leg comprises a plurality of straps (24a-c) adjustably extending from multiple strap mounting slots (see column 3, lines 49-54 and Figure below) in said respective upper and lower leg engagement portions, and strap to strap interengagement means (26) thereon. Regarding

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claim 10, the strap mounting slots further comprise oppositely disposed pairs of parallel spaced slots in longitudinally spaced relation (see Figure below) on said respective upper and lower leg engagement plates.

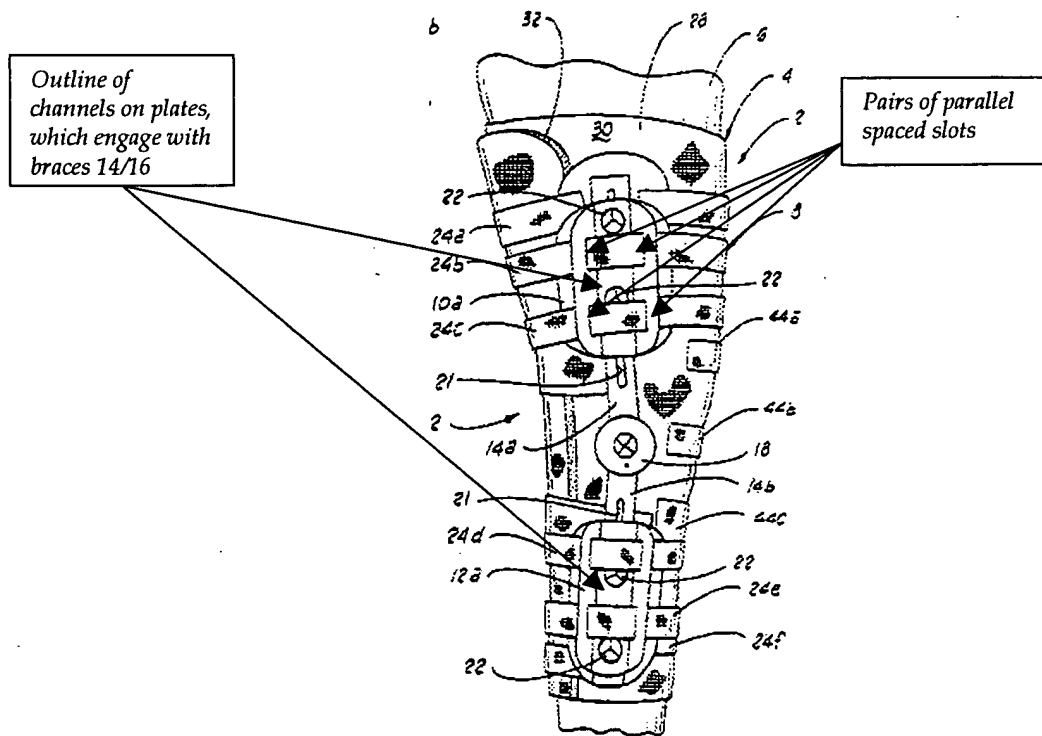
Regarding claim 6, the upper and lower leg engagement plates are transversely contoured to registerably engage the wearer's leg (see plates engaged against leg in Figures 1 and 2), and a mounting channel (see outlines of channel in Figure 2 below) is defined in each of said upper and lower leg engagement plates, wherein the channel of the leg engagement plates cooperates with the vertical braces (14/16) to allow vertical movement of the leg engagement plates along the braces.

Regarding claim 7, the knee stabilization means comprise a knee support pad (34) overlying the wearer's knee, and positioning and retaining straps (54a-b) extending from said knee support pad.

Regarding claim 8, the knee support pad and positioning and retaining straps have interengagement means (hook/loops) thereon and are adjustably secured to the upper and lower leg engagement plates (support pad's side 30 has hook sensitive material to attach with hooks on 10/12; straps 54a-b are secured to 10/12 via support pad 34 and also secure via hook/loop material at its ends).

Regarding claim 11, the knee stabilization means further comprises a reinforcement band (i.e., stitching 38) secured inwardly from the perimeter edge surface thereof, said band defining a knee alignment area there within (in that the reinforcement band aligns with the knee).

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Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brink in view of U.S. Patent Number 6,302,858 to DeToro et al.

Brink discloses an adjustable therapeutic brace for controlling the degree of motion of a person's knee joint and comprising rigid upper and lower leg engagement plates, and an adjustable locking hinge assembly extending between and interconnecting said upper and lower engagement plates. Brink does not disclose the specific components of the locking hinge.

DeToro et al. disclose a therapeutic brace for controlling the degree of motion of a person's ankle joint. The brace comprises an upper leg engagement plate (13) and lower foot engagement plate (14/15), fitted against the leg and foot of a user, respectively. DeToro et al. disclose a locking hinge extending between and interconnecting the upper and lower engagement plates, which allows selectively adjustable motion of the user's joint. The locking hinge assembly comprises an upper extremity element (26) and a lower extremity element (27) extending from said respective engagement plates, a free end of said upper extremity element adjustably engaged with a free end of said lower extremity element, wherein said engagement ends have C-shaped overlapping end portions (see Figure 11) with an adjustable apertured locking assembly thereon. The apertured locking assembly comprises an apertured hinge block (34) and an apertured compression cap (35) in aligned relationship to one another, fasteners (F) extending through said apertures thereof and through an elongated opening in each of said C-shaped overlapping end portions. DeToro et al. specifies that this locking arrangement allows incremental adjustment to the degree of motion permitted to the user's joint.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the therapeutic joint immobilization brace disclosed by Brink, wherein the locking hinge assembly includes the overlapping configuration and locking assembly taught by DeToro et al., to allow incremental adjustment to the degree of motion permitted by the braced joint.

17. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brink in view of U.S. Patent Number 6,302,858 to Smith, III.

Brink discloses an adjustable therapeutic knee immobilization brace for controlling the degree of motion to a person's knee comprising: a flexible sheet of cushion material, and rigid

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upper and lower leg engagement plates, fitted against the leg above and below the knee. Brink discloses that the brace is secured to the wearer's leg by a plurality of straps (24a-c) adjustably extending from multiple strap mounting slots in the upper and lower leg engagement portions. Brink does not specify that the straps be non-elastic.

Smith, III discloses a therapeutic knee brace that is secured to the wearer's leg with straps. Smith, III specifies that the straps be non-elastic, so that the strap will not stretch, and the brace cannot slide down the wearer's leg.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the therapeutic knee brace as disclosed by Brink, wherein the securement straps are made of non-elastic material, as taught by Smith, III, to securely attach the brace to the wearer's leg without sliding of the brace.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

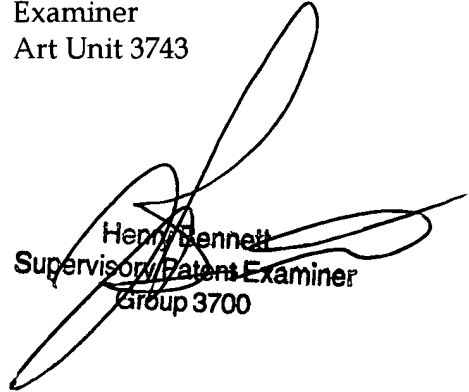
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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